

## **REMARKS**

### **Status of Claims**

Claims 15-31 are pending in this application. Based on the Remarks below, reconsideration and allowance are respectfully requested.

### **Double Patenting**

Applicants respectfully acknowledge that the double patenting rejection on the grounds of non-statutory obviousness-type double patenting over U.S. Patent No. 6,643,537 (“the ‘537 patent”) in view of Cain (US 5,984,368) has been overcome by the terminal disclaimer submitted.

### **Rejection of Claims under 35 U.S.C. § 102**

The Office Action maintained the rejection of Claims 15-17, 19-26, and 31 under 35 U.S.C. § 102(e) as being anticipated by Engleson et al. (U.S. Patent No. 6,671,563). Applicants respectfully traverse the rejection.

Engleson et al. does not teach and suggest each and every element as claimed in the application. For instance, Engleson et al. does not teach a fluid injection system that comprises an injector comprising two drive mechanisms and two illumination devices, respectively; two fluid containers that contain two fluids, respectively, and which are operably associated with the two drive mechanisms, respectively; and a control device that is operably associated with the drive mechanism, and comprises a computer screen having two elements affiliated with the two illumination devices, respectively, and wherein the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid.

Engleson et al., on the other hand, discloses and claims a system for collecting data and managing patient care. Engleson’s system includes visual displays and touch screens for interfacing with the system and allows for monitoring and adjusting the infusion pump by providing and evaluating status information of the pump on the display, and a color coded illumination device for indication of the status and schedule of each drug administration for each

patient. Engleson's system provides as an example of such color coding of a visual display to indicate the status and schedule of drug administration, a yellow band indication for the drug delivery window extending thirty minutes prior and thirty minutes after a scheduled time of administration. Engleson's system does not include an injection system including dual drive mechanisms with first and second different light colors corresponding to the first and second fluids, i.e., a dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid. In particular, Engleson et al. does not teach first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system.

Because Engleson et al. does not teach every element of the claimed invention, the claims defining the current invention are not anticipated by Engleson et al. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

### **Rejection of Claims under 35 U.S.C. § 103**

A. Claims 18 and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Engleson et al. in view of Uber et al. (U.S. Patent No. 5,494,036). Specifically, the Examiner has alleged that Engleson et al. uses a pump as an infusion system and does not disclose the use of a syringe having a plunger and a piston adapted to engage the plunger of the syringe. Uber et al., however, was alleged to disclose a contrast infusion system in which two motors are used to engage the plungers of two syringes inside the injector unit. Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Engleson et al. with the disclosure of Uber et al. and use a syringe system in place of the pump infusion system. Applicants respectfully traverse the rejection.

It should be pointed out that Claims 18 and 28 are dependent claims depending upon independent Claims 15 and 23, respectively, and further claim a feature of fluid container as being a syringe with a plunger and a piston. As discussed before, Engleson's system does not

provide an injection system including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid, as claimed in the independent Claims 15 and 23. Engleson's system provides as an example of color coding of a visual display to indicate the status and schedule of drug administration, a yellow band indication for the drug delivery window extending thirty minutes prior and thirty minutes after a scheduled time of administration. Engleson's system does not include an injection system including dual drive mechanisms with first and second different light colors corresponding to the first and second fluids.

Such deficiency is not cured by Uber et al. even though Uber et al. teaches a patient infusion system for use with MRI having dual-syringe arrangement. Uber et al. does not teach or suggest dual-syringes with dual-illumination devices, and a control device having dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid. Therefore, Engleson et al., alone or in combination with Uber et al., does not teach or suggest a dual illumination device with first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a crowded field where there is a great and long-felt need for quick and accurate determination of which fluids are being administered to a patient.

Because neither Engleson et al. nor Uber et al., alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Uber's infusion system and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) over Engleson et al. in view of Uber et al. be withdrawn.

B. Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Engleson et al. in view of Niehoff (U.S. Patent No. 5,681,286). Specifically, the Examiner has alleged that Engleson et al. discloses using a flashing icon to alert a problem with the infusion pump as well as using various icons, graphics, and text to monitor the status of the infusion pump. However, Engleson et al. fails to disclose explicitly using either a flashing, on, or off condition to signify the state of the system. Niehoff teaches the use of an LED as an indicator for an infusion system in which the LED flashes when the plunger is moving, is steady when the system is locked, and would be off when the system is off. Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed by Engleson et al. to use a flashing condition, a steady condition, and an off condition to signify the status of the injection system. Applicants respectfully traverse the rejection.

It should be pointed out that Claim 20 is a dependent claim, depending upon Claim 19 that depends on the independent Claim 15, and further claims a feature of a flashing condition, indicating various conditions, e.g., an armed state, a steady condition, or an off condition, of the system. As discussed before, Engleson's system does not provide an injection system including dual drive mechanisms, e.g., dual-syringe arrangement with two motors, with dual illumination devices, and a control device having computer touch screen and display with dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid, as claimed in the independent Claim 15. Engleson's system provides as an example of color coding of a visual display to indicate the status and schedule of drug administration, a yellow band indication for the drug delivery window extending thirty minutes prior and thirty minutes after a scheduled time of administration. Engleson's system does not include an injection system including dual drive mechanisms with first and second different light colors corresponding to the first and second fluids.

Such deficiency is not cured by Niehoff even though Niehoff teaches an LED indicator for various conditions for an infusion system, as the Examiner noticed. Like Uber et al, Niehoff

does not teach an injector system including dual-syringes with dual-illumination devices, and a control device having dual elements affiliated with the dual illumination devices so that the first illumination device and the first element emit a first light color corresponding to the first fluid and the second illumination device and the second element emit a second light color corresponding to the second fluid.

Therefore, Engleson et al., alone or in combination with Niehoff, does not teach or suggest first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a crowded field where there is a great and long-felt need for quick and accurate determination of which fluids are being administered to a patient.

Because neither Engleson et al. nor Niehoff, alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Niehoff's injector and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Engleson et al. in view of Niehoff be withdrawn.

C. Claims 27, 29, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Cain (U.S. Patent No. 5,984,368). Specifically, the Examiner has alleged that Engleson et al. does not disclose using the same color-coding used on the graphical display on the fluid containers themselves. However, Cain teaches that it is known in the art to match medications from a time chart to the medicine containers as well and further such charts may be "implemented as screen displays in a computer program." Accordingly, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to extend the color-coding already disclosed by Engleson et al. to the fluid containers themselves in light of the teachings of the reference by Cain to reduce the chance of confusing the fluid containers. Applicants respectfully traverse the rejection.

It should be pointed out that Claims 27, 29 and 30 are dependent claims, depending upon the method Claim 23 that is directed to a method of operating an injector system of the present

invention for providing a color coding corresponding to a programmed injection protocol, and further claim a feature of corresponding multiple color codings showing on the computer screen for flashing and/or contrast phases with the same multiple color codings for the fluid containers containing flashing and/or contrast phase medium, respectively. As discussed before, Engleson's system does not provide an injector system as claimed including dual drive mechanisms and different first and second light colors corresponding to first and second fluids. Engleson's system provides as an example of color coding of a visual display to indicate the status and schedule of drug administration, a yellow band indication for the drug delivery window extending thirty minutes prior and thirty minutes after a scheduled time of administration. Engleson's system does not include an injection system including dual drive mechanisms with first and second different light colors corresponding to the first and second fluids.

Moreover, such deficiency is not cured by Cain even though Cain teaches match medication from a time chart to the medicine containers, and the chart may be further implemented as screen displays in computer program. Cain does not teach a method for providing a color coding corresponding to a programmed injection protocol using an injector system, as claimed in the present invention. Therefore, Engleson et al., alone or in combination with Cain, does not teach or suggest first and second different light colors corresponding to each of the first and second different fluids in the dual-syringe arrangement of the present injection system. Such features provide a superior advantage for remote patient monitoring in a crowded field where there is a great and long-felt need for quick and accurate determination of which fluids are being administered to a patient.

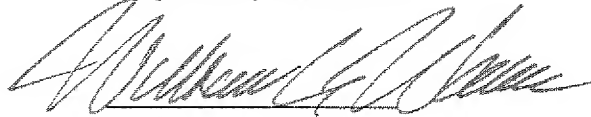
Because neither Engleson et al. nor Cain, alone or in combination, suggests each and every feature of the invention as claimed, it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Engleson's system with Cain's chart or screen displays and come up with the invention as claimed in the current application. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) over Engleson et al. in view of Cain be withdrawn.

In re Application of: Zatezalo et al.  
Serial No.: 10/698,047  
Filing Date: October 30, 2003  
Response to Final Office Action dated July 14, 2006

**Conclusions**

It is believed that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the examiner is encouraged to call the undersigned attorney at 404-853-8081.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William L. Warren', is written over a horizontal line.

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